AD_____

Award Number: DAMD17-99-1-9576

TITLE: Roundtable on Biomedical Engineering Materials and Application

PRINCIPAL INVESTIGATOR: Richard Chait, Ph.D.
Toni Marechaux, Ph.D.
Emily Ann Meyer

CONTRACTING ORGANIZATION: National Academy of Sciences
Washington, DC 20418

REPORT DATE: September 2003

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	September 2003	Final Addendum (1 Sep 2002 - 30 Aug 2003)

4. TITLE AND SUBTITLE
Roundtable on Biomedical Engineering Materials and Application

5. FUNDING NUMBERS
DAMD17-99-1-9576

6. AUTHOR(S)
Richard Chait, Ph.D.
Toni Marechaux, Ph.D.
Emily Ann Meyer

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
National Academy of Sciences
Washington, DC 20418

E-Mail: tthorowg@nas.edu; tmaracha@nas.edu; emeyer@nas.edu;

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)
The Biomedical Engineering Materials and Applications Roundtable held four meetings between October 2002 and September 2003.

Their sixth meeting was held December 19-20, 2002 in Washington, DC to plan for the Science-Based Testing Workshop. At that time, after finalizing a topic and speaker list, it was decided to reschedule the workshop from February to April.

The seventh meeting was held February 11, 2003 in Washington, DC. There the committee reviewed progress in planning the Science-Based Testing Workshop and discussed selection of a new chairperson.

The eighth meeting coincided with the Science-Based Testing Workshop on April 22-23, 2003 in Washington, DC. A proceeding is expected from that workshop later in the year.

The ninth meeting took place on July 14-15, 2003 in Woods Hole, MA. There the roundtable members set future plans and goals for the roundtable and heard two presentations.

14. SUBJECT TERMS
Biomedical, materials, roundtable

15. NUMBER OF PAGES
13

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

Introduction

The Biomedical Engineering Materials and Applications (BEMA) Roundtable will provide a forum for identifying major opportunities for applying engineering principles to create and improve clinical performance of medically useful materials and devices, including implants, as well as for discussion of strategies for overcoming obstacles—technical, legal, or cultural—that impede transition of new materials and devices to clinical application.

Body

Roundtable Meetings

The National Research Council-Institute of Medicine-National Academy of Engineering (NRC-IOM-NAE) held the sixth BEMA meeting on **19-20 December 2002** in Washington, DC. The objectives of the meeting were to: hear from speakers on reimbursement issues; plan for the workshop on science-based assessment; plan for future BEMA meetings. The invited speakers were Ron Geigle of Polidais (a policy consulting company that had undertaken a study on reimbursement for Advamed) and Marie Mindeman of the American Medical Association. BEMA members provided updates on the activities of their organizations. The possibility of BEMA being involved in the creation of a nonprofit to provide information dissemination for small biomaterials companies was discussed. However, it was determined that this was outside the scope of the BEMA activity. The Workshop on Science-Based Assessment was rescheduled for April 2003 in order to allow for the participation of important speakers. Speaker and invitee lists were further developed.

A teleconference was held on **8 February 2003** by the planning subcommittee for the Workshop on Science-Based Assessment. During this teleconference, the format of the meeting was determined so as to ensure maximum interaction among attendees and participation in discussions.

The seventh BEMA meeting was held on **11 February 2003** in Washington, DC. The primary purpose of the meeting was to continue to develop the agenda, speaker list, and invitee list for the Workshop on Science-Based Assessment. The theme of the workshop was further developed to focus on "Accelerating Product Development of Combination Medical Devices." It was agreed that some type of proceedings would be produced from the workshop and NRC staff were assigned the task of determining what type of document was possible under NRC policy. Robert Nerem, chair of BEMA since its inception, announced that he would have to step down on April 30, 2003 due to a potential perceived conflict of interest with his new position at the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Candidates for his successor were discussed, as well as potential new members for BEMA. Topics for the July BEMA meeting were considered and a planning subcommittee was created.

The workshop on "Science-Based Assessment: Accelerating Product Development of Combination Medical Devices" was held on **22-23 April 2003** in Washington, DC (see Appendix A for agenda and participant list). Approximately 50 individuals attended. The workshop began with introductory talks designed to set the context for discussion, followed by panel discussions on three different combination products: bone-morphogenetic proteins for orthopaedic repair, drug-eluting stents, and cell-matrix cartilage implants. Invited speakers were: John Watson, National Institutes of Health; Renu Virmani, Armed Forces Institute of Pathology; Paul Citron, Medtronic; Aric Kaiser, U.S. Food and Drug Administration; Darin Weber, U.S. Food and Drug Administration; Jim Rutledge, Datavision; Steve LaRiviere, The Boeing Company; Barbara Boyan, Georgia Institute of Technology; Amy LaForte, Stryker Biotech; Bill McKay, Medronic Sofamor Danek; Robert Schwartz, Minnesota Cardiovascular Research Institute; Semih Oktay, Cardiomed; Ronald Sahatjian, Boston Scientific Corporation; William Costerton, Montana State University; Leonard Weber, University of Detroit; Richard Coutts, University of California at San Diego; Jim Burns, Genzyme; and Anthony Ratfcliffe, Synthasome, Inc. Panel chairs were Joshua Jacobs, Rush Medical College; Terry Woods, U.S. Food and Drug Administration; and Crystal Cunanan, Edwards Lifesciences.

A teleconference was held on **12 June 2003** by the planning subcommittee for the July 2003 BEMA meeting. Buddy Ratner of the University of Washington, who was approved by the NRC as chair of BEMA in May 2003, presided over the teleconference. It was decided that the meeting would focus on methods for determining the (economic) value to the patient/society/industry of a medical device technology. Speakers were suggested. It was agreed that the proceedings from the April workshop should be produced in CD format, rather than hardcopy, and that the BEMA members should receive a draft copy prior to the July BEMA meeting.

The ninth BEMA meeting was held on **14-15 July 2003** at the J. Erik Jonsson Woods Hole Center in Woods Hole, MA. The primary objectives of the workshop were to hear from speakers on methods of forecasting the potential value of new medical device technologies and to discuss the future plans for the roundtable. Invited speakers were Peter Nicholas, co-founder and chairman of the board of Boston Scientific Corporation, and Robert Ward, president and chief executive officer of The Polymer Technology Group. Highly positive feedback was received from the April workshop and follow-on topics, such as improvements in animal modeling, were discussed. Dick Swaja of NIBIB led a discussion of how NIBIB could better interact with industry.

The tenth BEMA meeting is scheduled for 28-29 October 2003 in Washington, DC. Planned topics for discussion include the membership of BEMA in 2004 and the topic for the third BEMA workshop, which will most likely be held in October 2004.

Key Research Accomplishments

- The BEMA workshop on "Science-Based Assessment: Accelerating Product Development of Combination Medical Devices" was held, including panels on the clinical and industry perspective on assessment of three combination products:

bone-morphogenetic proteins for use in orthopaedic repair; drug-eluting stents; and cell-matrix cartilage implants.

- A workshop proceedings in CD format is in publication and scheduled for release in late 2003.
- Three additional BEMA meetings were held with speaker presentations covering: the impact of reimbursement policies on the biomedical device industry; and determination of the value to the patient/society/industry of medical device technologies.
- Buddy Ratner of the University of Washington succeeded Robert Nerem as BEMA chair.

Reportable Outcomes

Workshop Presentations by

- John Watson, National Institute of Health, **"Setting the Context: Scientist/Engineer"**
- Renu Virmani, Armed Forces Institute of Pathology, **"Setting the Context: Clinician"**
- Paul Citron, Medtronic, **"Setting the Context: Risk/Benefit Ratio"**
- Aric Kaiser, U.S. Food and Drug Administration, **"Science-Based Testing for Devices"**
- Darin Weber, U.S. Food and Drug Administration, **"Science-Based Testing for Biologics"**
- Jim Rutledge, Datavision, **"Experimental Design Technologies"**
- Steve LaRiviere, The Boeing Company, **"Scientific and Process Design"**
- Barbara Boyan, Georgia Institute of Technology, **"Overview of Science and Test Methods: Bonemorphgenetic Proteins"**
- Amy LaFort, Stryker Biotech, **"Industry Presentation: Bonemorphgenetic Proteins"**
- Bill McKay, Medtronic Sofamor Danek, **"Industry Presentation: Bonemorphogenetic Proteins"**
- Robert Schwartz, Minnesota Cardiovascular Research Institute, **"Clinician Presentation: Drug-Eluting Stents"**
- Semih Oktay, Cardiomed, **"Industry Presentation: Drug-Eluting Stents"**
- Ron Sahatjian, Boston Scientific Corporation, **"Industry Presentation: Drug-Eluting Stents"**
- William Costerton, Montana State University, **"Biofilms and Biomedical Devices"**
- Leonard Weber, University of Detroit, **"Ethics Presentation"**
- Richard Coutts, University of California at San Diego, **"Clinician Presentation: Cell-Matrix Cartilage Implants"**
- Jim Burns, Genzyme, **"Industry Presentation: Cell-Matrix Cartilage Implants"**

- Anthony Ratcliffe, Synthasome, Inc., **"Industry Presentation: Cell-Matrix Cartilage Implants"**

Meeting Presentations by:

- Marie Mindeman, American Medical Association, **"Current Procedural Terminology (CPT) Editorial Process"**
- Ron Geigle, Consultant, Polidais, **"Reimbursement Issues Related to Biomedical Devices and Biotechnology"**
- Pete Nicholas, Co-Founder and Chairman of the Board, Boston Scientific Corporation, **"Industry Perspective on Risk and Innovation in the Medical Device Industry"**
- Robert Ward, President and CEO, The Polymer Technology Group, **"Industry Perspective on Biomaterials in the Medical Device Industry"**

Conclusions

The BEMA Roundtable held one workshop on science-based assessment and three meetings where speakers covered the impact of reimbursement policies on the biomedical device industry and determination of the value to the patient/society/industry of medical device technologies. A workshop proceedings is scheduled to be released publicly in late 2003. Buddy Ratner of the University of Washington replaced Robert Nerem of the Georgia Institute of Technology as chair of BEMA. BEMA plans to meet again in October 2003 to discuss topics for future meetings and the next workshop, currently scheduled for the fall of 2004.

Appendix A

"Science-Based Assessment: Accelerating Product Development of Combination Medical Devices"

April 22-23, 2003
National Academy of Sciences
2101 Constitution Avenue, NW
Washington, DC

AGENDA

Day 1: Tuesday, April 22, 2003		**NAS Building, Lecture Room**
7:45 AM	*Continental Breakfast*	
8:30 AM	Welcome & Introduction	Robert Nerem, BEMA Chair
8:35 AM	Setting the Context: Scientist/Engineer	John Watson, NIH
8:55 AM	Setting the Context: Clinician	Renu Virmani, Armed Forces Institute of Pathology
9:15 AM	Setting the Context: Risk/Benefit Ratio	Paul Citron, Medtronic
9:35 AM	Discussion	All
10:00 AM	*Break*	
10:30 AM	Science-based Testing for Devices	Aric Kaiser, FDA
10:45 AM	Science-based Testing for Biologics	Darin Weber, FDA
11:00 AM	Experimental Design Technologies	Jim Rutledge, Datavision
11:30 PM	Discussion	All
12 NOON	*Lunch*	
1:00 PM	Scientific & Process Design	Steve LaRiviere, Boeing
1:30 PM	Discussion	All
1:45 PM	BMP-Orthopaedic Repair	Session Chair: Joshua Jacobs, Rush Medical College
1:45 PM	Overview of Science & Test Methods	Barbara Boyan, Georgia Institute of Technology
2:05 PM	Industry Presentation	Amy LaForte, Stryker Biotech
2:25 PM	Industry Presentation	Bill McKay, Medtronic Sofamor Danek

2:45 PM	Discussion	All
3:15 PM	*Break*	
3:45 PM	Drug-Eluting Stents	Session Chair: Terry Woods, FDA
3:45 PM	Clinician Presentation	Robert Schwartz, MD, Minnesota Cardiovascular Research Institute
4:05 PM	Industry Presentation	Semih Oktay, Cardiomed
4:25 PM	Industry Presentation	Ronald Sahatjian, Boston Scientific Corporation
4:45 PM	Discussion	All
5:15 PM	*Break*	
5:30 PM	Biofilms and Medical Devices	William Costerton, Montana State University
6:15 PM	*Reception*	Great Hall, NAS Building
7:15 PM	*Adjourn*	
Day 2: Wednesday, April 23, 2003		**NAS Building, Lecture Room**
7:45 AM	*Continental Breakfast*	All
8:30 AM	Ethics Presentation	Leonard Weber, University of Detroit
9:00 AM	Cell-Matrix Cartilage Implants	Session Chair: Crystal Cunanan, Edwards Lifesciences
9:00 AM	Clinician Presentation	Richard Coutts, University of California at San Diego
9:20 AM	Industry Presentation	Jim Burns, Genzyme
9:40 AM	Industry Presentation	Anthony Ratcliffe, Synthasome Inc.
10:00 AM	Discussion	All
10:30 AM	*Break*	
11:00 AM	General Discussion	All
12 NOON	*Adjourn*	

NMAB Roundtable on
Biomedical Engineering Materials and Applications

Science-Based Assessment:
Accelerating Product Development of Combination Medical Devices

Attendance List

James Anderson
CWRM

Craig Blaschke
BioMet, Inc.

Barbara Boyan
Georgia Institute of Technology

Jim Burns
Genzyme

Dennis Chamot
NRC - Division on Engineering and Physical Sciences

Erica Check
Nature

Bill Christianson
DePuy AcroMed

Paul Citron
Medtronic

Bill Costerton
Montana State University

Arthur Coury
Genzyme

Richard Coutts
University of California at San Diego

Crystal Cunanan
Edwards Lifesciences Corporation

A. Stephen Dahms
California State University Program for Education and Research in Biotechnology (CSUPERB)

Robert Dorsch
DuPont

Charles Dufor
U.S. Food and Drug Administration

Lise Duran
SurModics, Inc.

Tara Federici
AdvaMed

David Feigal
U.S. Food and Drug Administration

Marilyn Field
Institute of Medicine

Donald Fink
U.S. Food and Drug Administration

Gary Fischman
NMAB Board Liaison

Susan Gamble
Edwards Lifesciences

Alan Goldstein
Alfred University

Jen Goode
U.S. Food and Drug Administration

Florence Haseltine
National Institutes of Health

Peter Hudson
U.S. Food and Drug Administration

Joshua Jacobs
Rush Medical College

Aric Kaiser
U.S. Food and Drug Administration

Sunita Kaushik
NRC – National Materials Advisory Board

Christine Kelley
National Institutes of Health

James Killian
NRC - National Materials Advisory Board

Toni Kingsley
Zimmer, Inc.

Mark Kramer
U.S. Food and Drug Administration

Amy LaForte
Stryker Biotech

Steve Larivieri
Boeing

Carol Lucas
National Science Foundation

Toni Maréchaux
NRC – National Materials Advisory Board

Meg McCoy
Institute of Medicine

Bill McKay
Medtronic Sofamor Danek

Emily Ann Meyer
NRC – National Materials Advisory Board

Robert Nerem
Georgia Institute of Technology

Semih Oktay
Cardiomed

Jack Parr
Wright Medical Technology, Inc.

Sohi Rastegar
National Science Foundation

Anthony Ratcliffe
Synthasome, Inc.

Buddy Ratner
University of Washington

Dianne Rekow
Associated Institutions for Material Science (AIMS)

Jonathan Jay Rosen
Center for Integration of Medicine and Innovative Technology (CIMIT)
Jim Rutledge
Datavision

Ronald Sahatjian
Boston Scientific

Bonnie Scarborough
NRC – National Materials Advisory Board

Robert Schmitt
Dow Chemical Company

Robert Schwartz
Minneapolis Heart Institute

Renu Virmani
Armed Forces Institute of Pathology

John Watson
National Insititutes of Health

Darin Weber
U.S. Food and Drug Administration

Leonard Weber
University of Detroit

Michael Weinrich
National Institutes of Health

Terry Woods
U.S. Food and Drug Administration